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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,474

11/20/2003

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EXAMINER

MEYERS, MATTHEW S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/716,474	Applicant(s) KIKUCHI ET AL.	
	Examiner MATTHEW S. MEYERS	Art Unit 3689	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's communication on 6/11/08, wherein claims 1-3 and 5-9 are currently pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/08 has been entered.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).
4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted is being considered by the examiner.

Specification

6. The amendment filed 6/11/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 1 refers to a “a control section for changing an operation sequence of said automatic analyzer to prevent the occurrence of the cross-contamination on the basis of said reagent cross-contamination information stored in said memory.” Examiner is unable to determine in the specification where applicant has support for a controller to change an operation other than original claim 6 which indicates this change is being preformed by a plurality of information receivers.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See objection above.

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8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner is unable to determine what applicant is claiming by a "control section"?

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 101 because under the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

Presently, Claim 1 recites. "a control section for changing an operation sequence of said automatic analyzer..." which Examiner is unable to find support for in the specification. Due to this ambiguity, Examiner believes this control to be performed by "information receivers" which Examiner has previously construed to be a human being.

Thus, claim 1, and its dependents are directed towards non-statutory subject matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3 and 5-9 rejected under 35 U.S.C. 102(e) as being anticipated by Mault (Pub. No.: US 2003/0129578).

13. With respect to **Claim 1**:

Mault discloses a system comprising:

a maintenance computer storing reagent cross-contamination information (Mault [0006], "...the central computer, upon communication therewith being established by any of the individuals, directs a series of inquiries to the respective individuals requesting responses to be transmitted to the central computer.");

an automatic analyzer connected to said maintenance computer through a communication line said automatic analyzer including (Mault [0007], "Various local input devices may be used to transmit this information to the central computer, including mobile telephones, personal digital assistants (PDAs), personal computers, desktop appliances, interactive TVs, and health condition

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monitors, such as temperature measuring devices, blood pressure measuring devices, respiratory analyzers, etc.”):

a memory storing reagent cross-contamination information transmitted from said maintenance computer (Mault, Fig. 2), and

a control section for changing an operation sequence of said automatic analyzer to prevent the occurrence of the cross-contamination on the basis of said reagent cross-contamination information stored in said memory (Mault [0006], “...the central computer, upon communication therewith being established by any of the individuals, directs a series of inquiries to the respective individuals requesting responses to be transmitted to the central computer.”).

1. With respect to **Claim 2**:

Mault discloses a system according to claim 1, wherein said maintenance computer is configured to carry out a validation test based on the collected cross-contaminated information to validate whether the information is true or false, and to send only the information, which has been validated as being true, to a plurality of other automatic analyzers each connected to said maintenance computer through a communication line (Mault Fig. 4, item 43, “Server software analyzes data”) While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because

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the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); < *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Here, Mault's system would be capable of carry out a validation test based on the collected information (Mault [0040-0042]).

2. With respect to **Claim 3**:

Mault discloses a system according to claim 2, wherein said maintenance computer is configured to collect the information and to carry out a validation test on the collected information, and to manage the information, which has been collected and subjected to the validation test, and to send the information to said plurality of other automatic analyzers (Mault Fig. 4, item 44, "Server software generates feedback, alerts").

3. With respect to **Claim 4**:

Cancelled.

4. With respect to **Claim 5**:

Mault discloses a system according to claim 1, wherein the cross-contamination information contains at least one of information for identifying an offensive reagent, information for identifying a defensive reagent, information regarding a level of influence of the cross-contamination, information regarding a contamination place, information regarding a detergent type, and information regarding a detergent volume (Mault [0028],

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“Each local input device, or some of them, includes a memory for storing data, a display for displaying such data, and an interface for interfacing the local input device with the communication network for transmission to the central computer.” and [0028] “By integrating the instantaneous flow volume with the instantaneous oxygen partial pressure, the oxygen uptake of the user can be calculated. Inclusion of additional gas sensors for carbon dioxide, nitric oxide, ketones, and other gases can be included to provide quantification of additional physiological parameters.”).

5. With respect to **Claim 6:**

Mault discloses a system according to claim 1, wherein each of said plurality of other automatic analyzers is configured to automatically take in the cross-contamination information and change an operation of said analyzer as required. (Mault Fig. 3, item 21, “Processor” and [0006], “...the central computer, upon communication therewith being established by any of the individuals, directs a series of inquiries to the respective individuals requesting responses to be transmitted to the central computer.”)).

6. With respect to **Claim 7:**

Mault discloses a system according to claim 6, wherein each of said other automatic analyzers is configured to display the information having been automatically taken in, to ask an operator of said analyzer whether the operation sequence of said analyzer is to be changed to register a result of confirmation made by the operator, and to change the operation sequence of said analyzer in accordance with the registration result (Mault Fig. 3, item 28, “Display”).

7. With respect to **Claim 8:**

Mault discloses a system according to claim 6, wherein each of said other automatic analyzers is configured to validate its own ability of the function of suppressing cross-contamination, and the to determine whether or not the operation sequence of each of said analyzers is to be changed or not, based on a combination of the validated ability of suppressing cross-contamination and the cross-contamination information having been automatically taken in (Mault [0009], "The outputs produced by the central computer, based on the statistical analysis of the inputted information, could include directing the individual to a healthcare agency, such as a hospital or a physician; directing the delivery of selected medications to selected areas; alerting healthcare officials to a particular health condition in a particular geographical location; and/or the issuance of statistical reports based on the statistical analysis.").

8. With respect to **Claim 9:**

Mault discloses a system according to claim 1, further including a processing system for enabling said maintenance computer to receive predetermined charges in exchange for offering said cross-contamination information (Mault Fig. 3, item 21, "Processor").

Response to Arguments

14. Applicant's arguments filed 6/11/08 have been fully considered but they are not persuasive. Applicant's arguments have been address above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW S. MEYERS whose telephone number is (571)272-7943. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan Mooneyham can be reached on (571) 272-6805. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew S Meyers/
Examiner, Art Unit 3689

/Janice A. Mooneyham/
Supervisory Patent Examiner, Art Unit 3689

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